Examiner Kosar: As stated briefly this morning, none of the newly applied references disclose that the desmopressin doses they disclose can, necessarily do, or that it may be desirable to, deliver desmopressin to produce a maximum blood concentration of about 10 pg/ml, and all pending rejected claims, one way or another, are intended to require the dosage forms to establish a blood concentration in the recited low dose ranges. I can only conclude that you must consider the wording of the claims insufficiently limiting in this respect, and I believe you indicated some level of agreement with this.

My notion is that you consider the "adapted for" and "sufficient to" language leaves the claims open to cover the prior art dosage forms you cite. Accordingly, I propose to delete the "adapted for" language and to insert language requiring more explicitly that the dose forms when administered *must* establish the concentration range and no other. Instead of using the language "*adapted for*" and "*sufficient to* establish," all of the claims proposed below affirmatively recite specific types of dosage forms and *require* that they establish serum concentrations in the critical range.

What do you think?

1. (As currently pending) A pharmaceutical composition comprising 0.5 ng to 20 µg desmopressin and a pharmaceutically acceptable carrier in a dosage form *adapted for* intranasal, transdermal, or intradermal administration *sufficient to establish* in a patient a steady plasma/serum desmopressin concentration in the range of from about 0.1 picograms desmopressin per ml plasma/serum to about a maximum of 10.0 picograms desmopressin per ml plasma/serum and to decrease urine production.

Proposed amendments:

1. (Amended) An intranasal, transdermal, or intradermal desmopressin dosage form ~~pharmaceutical composition~~ comprising 0.5 ng to 20 µg desmopressin and a pharmaceutically acceptable carrier ~~in a dosage form adapted for intranasal, transdermal, or intradermal administration sufficient to establish in~~ which when administered to a patient establishes a steady plasma/serum desmopressin concentration in the range of from about 0.1 picograms desmopressin per ml plasma/serum to about a maximum of 10.0 picograms desmopressin per ml plasma/serum and ~~to decrease~~ decreases urine production.

Alternative claim 1

1. (Currently amended) An intranasal, transdermal, or intradermal dosage form ~~pharmaceutical composition~~ comprising 0.5 ng to 20 µg desmopressin and a pharmaceutically acceptable carrier ~~in a dosage form adapted for intranasal, transdermal, or intradermal administration sufficient to establish in~~ which when administered to a patient in accordance with packaged instructions establishes a steady plasma/serum desmopressin concentration in the range of from about 0.1 picograms desmopressin per

ml plasma/serum to about a maximum of 10.0 picograms desmopressin per ml plasma/serum and ~~to decrease~~ decreases urine production.

2. (Cancelled)

3. (Amended) The ~~pharmaceutical composition~~ dosage form of claim 1 comprising from about 0.05 µg to about 10 µg desmopressin.

4. (Amended) The ~~pharmaceutical composition~~ dosage form of claim 1 comprising from about 0.1 µg to about 2 µg desmopressin.

5. (Cancelled)

6. (Amended) The ~~pharmaceutical composition~~ dosage form of claim 1 ~~in a dosage form adapted for transdermal delivery~~ for application to the skin comprising a patch, gel, cream, ointment, or iontophore.

7. (Amended) The ~~pharmaceutical composition~~ dosage form of claim 1 ~~adapted for transdermal administration~~ for application to the skin comprising ~~a~~ an intradermal patch.

8. (Cancelled)

9. (Amended) The ~~pharmaceutical composition~~ dosage form of claim 1 ~~in a dosage form sufficient to establish~~ which establishes in a patient a steady plasma/serum desmopressin concentration of from about 0.5 picograms desmopressin per ml plasma/serum to about 5.0 picograms desmopressin per ml plasma/serum.

10-26 (Cancelled)

27. (Amended) An ~~pharmaceutical~~ intranasal dosage form comprising desmopressin and a pharmaceutically acceptable carrier ~~adapted for intranasal administration~~ which when administered intranasally to a patient establishes a steady plasma/serum desmopressin concentration in the range of from about 0.1 picograms desmopressin per ml plasma/serum to about a maximum of 10.0 picograms desmopressin per ml plasma/serum for a time between four and six hours and decreases urine production.

28. (Amended) The ~~composition~~ dosage form of claim 27 which establishes in a patient a steady plasma/serum desmopressin concentration of from about 0.5 picograms desmopressin per ml plasma/serum to about 5.0 picograms desmopressin per ml plasma/serum.

29. (Amended) An intradermal or transdermal pharmaceutical dosage form comprising desmopressin and a pharmaceutically acceptable carrier ~~for intranasal or transdermal administration~~ which when administered intradermally or transdermally to a patient in

accordance with packaged instructions establishes a steady plasma/serum desmopressin concentration in the range of from about 0.1 picograms desmopressin per ml plasma/serum to about a maximum of 10.0 picograms desmopressin per ml plasma/serum for a time between four and six hours and decreases urine production.

30. (Previously submitted) The dosage form of claim 29 which establishes a steady plasma/serum desmopressin concentration of from about 0.5 picograms desmopressin per ml plasma/serum to about 5.0 picograms desmopressin per ml plasma/serum.

31. (Previously submitted) The dosage form of claim 29 comprising between 0.05 μg and 10 μg desmopressin.

32. (Amended) The dosage form of claim 29 ~~adapted for~~ comprising an intradermal ~~administration comprising a~~ patch.

33. (Amended) The dosage form of claim 29 ~~adapted for transdermal delivery and~~ comprising a patch, gel, cream, ointment, or iontophore.